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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/590,690	05/21/2007	Rosanne D. Dunn	29729/38914	2874

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EXAMINER	
SCHWADRON, RONALD B	
ART UNIT	PAPER NUMBER
1644	

NOTIFICATION DATE	DELIVERY MODE
03/30/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mgbdocket@marshallip.com

Office Action Summary	Application No.	Applicant(s)	
	10/590,690	DUNN ET AL.	
	Examiner	Art Unit	
	Ron Schwadron, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *28-48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *28-48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/13/10 has been entered.

2. The petition of 2/9/11 will be forwarded to the appropriate Office for consideration. The instant Office Action will not address the material addressed in said petition (which relates to a copy of an older set of the claims and related amendment which were apparently erroneously filed).

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 28-38,43,44,47,48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Uhr et al. (US Patent 4,792,447) in view of Raison et al. (WO 03/004056), Stavnezer et al. and Abe et al.

Uhr et al. teach antibody against lambda light chain wherein said antibody binds lambda light chain on tumor cells and wherein said antibody is conjugated to a toxin(see column 4, first paragraph and column 3, first paragraph and last paragraph). The antibody is labeled with a detectable moiety (aka a toxin). The conjugate is prepared in a diluent (for example see column 8, first complete paragraph). The conjugate is used to treat B cell tumors including B cell leukemia/lymphoma (see column 3, first paragraph and column 1, third paragraph). Uhr et al. disclose the method of claim 38 wherein the autologous bone marrow contains hematopoietic progenitor cells (see column 14, first paragraph). The method of Uhr et al. uses a chemotherapeutic agent (see column 15, second paragraph), wherein chemotherapeutic agents have the functional effect recited in claim 36 (see claim 37). Uhr et al. do not teach that said method can be used to treat multiple myeloma or that the antibody used binds free lambda light chain but does not bind intact Ig associated lambda chain. Raison et al. discloses that malignant B cells in multiple myeloma patients can produce light chains of kappa or lambda (see page 1, penultimate paragraph). The aformentioned are the two known alleles of Ig light chain. Raison et al. disclose that kappa light chain expressing myeloma cells are found which express free kappa light chain on the cell surface (see page 1, last paragraph) and that antibodies which bind said molecule can be used to treat such tumors (see page 2, second paragraph). In view of the fact that kappa and light chains are the two known alleles of Ig light chain, it would have been expected by a routineer that lambda light chain expressing myeloma cells would have been found which express free lambda light chain on the cell surface. In addition, Stavnezer et al. teach that free Ig lambda light chain can be expressed on the surface of a leukemia tumor cell (see abstract and page 3980, first column, last paragraph, continued on next page). Abe et al. disclose antibodies which bind free lambda light chain but does not bind intact Ig associated lambda chain (see Table 3).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Uhr et al. teach antibody conjugate against lambda light chain wherein said antibody binds lambda light chain on tumor cells and wherein the conjugate is used to treat B cell tumors whilst Raison et al. discloses that malignant B cells in multiple myeloma patients can produce light chains of kappa or lambda wherein the aformentioned molecules are the two known alleles of Ig light chain and that kappa light chain expressing myeloma cells are

found which express free kappa light chain on the cell surface and that antibodies which bind said molecule can be used to treat such tumors whilst in view of the fact that kappa and light chains are the two known alleles of Ig light chain, it would have been expected by a routineer that lambda light chain expressing myeloma cells would have been found which express free lambda light chain on the cell surface, Stavnezer et al. teach that free Ig lambda light chain can be expressed on the surface of a leukemia tumor cell and Abe et al. disclose antibodies which bind free lambda light chain but does not bind Ig associated lambda chain. One of ordinary skill in the art at the time the invention was made would have been motivated to the aforementioned because Uhr et al. teach antibody conjugate against lambda light chain wherein said antibody binds lambda light chain on tumor cells and wherein the conjugate is used to treat B cell tumors whilst in view of the teachings of Raison et al. and Stavnezer et al. that free Ig lambda light chain can be expressed on the surface of a leukemia tumor cell, it would have been expected by a routineer that lambda light chain expressing myeloma cells would have been found which express free lambda light chain on the cell surface and Abe et al. disclose antibodies which bind free lambda light chain but does not bind Ig associated lambda chain. In KSR Int'l Co. v. Teleflex Inc., 550 U.S. m, 2007 WL 1237837, at "13 (2007) it was stated that **"if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill"**.

Regarding applicants comments about the Jennings declaration, Stavnezer et al. teach that free Ig lambda light chain can be expressed on the surface of a leukemia tumor cell (see abstract and page 3980, first column, last paragraph, continued on next page). Regarding applicants comments and the Jennings 1.132 declaration, said declaration refers to a variety of publications published after the effective filing date of the instant application. However, the MPEP section 2143.02 (III) states:

III. PREDICTABILITY IS DETERMINED **AT THE TIME** THE INVENTION WAS MADE

Whether an art is predictable or whether the proposed modification or combination of the prior art has a reasonable expectation of success is determined *at the time the invention was made*. Ex parte Erlich, 3 USPQ2d 1011 (Bd. Pat. App. & Inter. 1986)

(Although an earlier case reversed a rejection because of unpredictability in the field of monoclonal antibodies, the court found "in this case at the time this invention was made, one of ordinary skill in the art would have been motivated to produce monoclonal antibodies specific for human fibroblast interferon using the method of [the prior art] with a reasonable expectation of success." 3 USPQ2d at 1016 (emphasis in original).).
Thus, comments made regarding said publications are not germane to the issue of reasonable expectation of success/predictability and the instant rejection. Furthermore, the Jennings declaration refers to a complete set of references and cannot be evaluated without evaluating all of the cited references. Regarding applicants comments about paragraph 17 of the Jennings declaration, said passage refers to one of the aforementioned publications filed after the effective filing date of the insatnt application. In addition, said comments ignore the fact that surface bound kappa light was already known in the art. Regarding the various cited differences between kappa and lambda light chain, both sets of light chain are structurally similar in the ability to form dimers with Ig heavy chain. Furthermore, in view of the ability of both types of light chains to associate with heavy chain it would be reasonable to conclude that kappa and lambda light chains would have a similar ability to associate with molecules other than Ig heavy chain. In addition, Stavnezer et al. teach that free Ig lambda light chain can be expressed on the surface of a leukemia tumor cell (see abstract and page 3980, first column, last paragraph, continued on next page).

5. Claims 39-42,45,46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Uhr et al. (US Patent 4,792,447) in view of Raison et al. (WO 03/004056) and Abe et al. as applied to claims 28-38, 43,44,47,48 above, and further in view of Ruben et al. (US 2005/0255532.

The previous rejection renders obvious the claimed inventions except for the method of claims 39-42 or antibodies of claims 45,46. Ruben et al. teach therapeutic use of chimeric antibodies (see [0029] and [0218]). Ruben et al. teach in vivo diagnostic use of an antitumor antibody labeled with a radioisotope (see [0261] and [0362]). Ruben et al. teach that the antibody can be conjugated to heterologous polypeptides or nucleic acids encoding such molecules such as cytokines (see [0261],[0294],[0373],[0375],[0440],[0366]). It would have been prima facie obvious to

one of ordinary skill in the art at the time the invention was made to have created the claimed invention because the previous rejection renders obvious the claimed inventions except for the method of claims 39-42 or antibodies of claims 45,46 whilst Ruben et al. teach therapeutic use of chimeric antibodies, in vivo diagnostic use of an antitumor antibody labeled with a radioisotope and that the antibody can be conjugated to heterologous polypeptides or nucleic acids encoding such molecules such as cytokines. A routineer would have treated the autologous cell transplant recipient with the antilambda antibody to kill tumor cells present in the recipient. One of ordinary skill in the art at the time the invention was made would have been motivated to do the aforementioned because Ruben et al. teach therapeutic use of chimeric antibodies, in vivo diagnostic use of an antitumor antibody labeled with a radioisotope and that the antibody can be conjugated to heterologous polypeptides or nucleic acids encoding such molecules such as cytokines and a routineer would have treated the autologous cell transplant recipient with the antilambda antibody to kill tumor cells present in the recipient. In KSR Int'l Co. v. Teleflex Inc., 550 U.S. m, 2007 WL 1237837, at "13 (2007) it was stated that **"if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill"**.

Applicants arguments are as per addressed above.

6. No claims are allowed.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ron Schwadron, Ph.D. whose telephone number is (571)272-0851. The examiner can normally be reached on Monday-Thursday 7:30-6:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 571 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ron Schwadron/
Ron Schwadron, Ph.D.
Primary Examiner, Art Unit 1644